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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,795	04/04/2001	Staffan Folestad	1103326-0660	6487

7470 7590 01/23/2004

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NEW YORK, NY 10036

EXAMINER	
TSOY, ELENA	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/806,795	FOLESTAD ET AL.
	Examiner	Art Unit
	Elena Tsoy	1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 4-20, 22-25, 27-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-20,22-25 and 27-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

Amendment filed on November 3, 2003 has been entered. Claims 3 and 26 have been cancelled. Claims 1, 2, 4-20, 22-25, 27-53 are pending in the application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 4-20, 22-25, 27-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Hammann et al, further in view of Naqwi (US 5,784,160), and further in view of Applicants' admitted art of Link et al.

Drennen, III et al disclose a method and apparatus for monitoring the formation of a coating on a single article such as drug unit (particle) (See column 2, lines 1-5; column 3, lines 44-48), comprising the steps of: arranging the articles at a given spatial location in a fluidized bed by fluidizing the particles on an upwardly directed flow (See Fig. 2; column 4, lines 36-38); forming said coating on the particles by spraying the particles with a coating material through nozzle (See column 3, lines 65-67); and monitoring on-line (continuously) (See column 2, lines 65-67; column 3, lines 60-62) by retrieving the single article into a recess of a probe and carrying out measurement on said coating by a near-infrared spectrometric to obtain a value of at least once principle parameter related to said coating such as amount of coating or coating thickness (See Abstract; column 2, lines 55-60). A coating apparatus comprises air distribution plate in the

lower region with a flow of air within the apparatus so that air will flow between the particle and a measurement unit (shielding gas) (See Fig. 1; column 4, lines 35-45).

Drennen, III et al fail to teach that the spectrometric measurement on particles is performed in situ while coating is being formed.

Hammann et al teach that it is known in the art that the characteristics of particles flowing in gas can be advantageously monitored *in situ* using optical methods based on analysis either of the scattered light using light of various wavelength (See column 1, lines 25-45) or extinction of light (See column 1, lines 63-67). Some measurements require calibration of instruments on a single particle using all relevant types of particles that might be encountered, immersed in the fluid under investigation (See column 2, lines 11-19). Another method of particle size measurement, which may be used with single particles or groups of few particles, is microscopy in combination with image analysis. While microscopy gives the most complete information about particle size and shape, for small particles expensive high-quality optics and high-speed image processing is necessary for in situ on-line measurements of particles immersed in a fluid (See column 2, lines 21-31); and in contrast to optical methods of prior art, optical particle size analyzer based on coherent laser beam may be used for in situ in real time measuring irregularly shaped particles (See column 2, lines 32-50) to ensure process quality (See column 2, lines 45-47). Liquid droplets can be also investigated by optical methods (See column 6, line 18). In other words, a secondary reference of Hammann et al is relied upon to show that in situ optical methods include known methods based on scattered light or extinction of light of various wavelengths. One of ordinary skill in the art at would know that known methods include near-infrared spectrometry, Raman scattering.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used various in-situ optical methods described by Hammann et al for monitoring particles of Drennen, III et al *while* the coating is being formed, with the expectation of providing the desired fast control of the process, since Hammann et al teach that the characteristics of particles flowing in gas can advantageously be monitored *in situ* by illuminating particles with light.

Drennen, III et al in view of Hammann et al fail to teach that in situ monitoring of coating process is made on a single particle or plurality of particles in a model fluidized bed for obtaining optimum process parameters related to coating in order to control coating process in a real industrial scale fluidized bed.

Naqwi teaches that size of multiple particles can be monitored *in situ* by first obtaining calibration data on a single particle or plurality of particles (See Figs. 7, 8; column 8, lines 5-15). In the calibration mode, using particles of known sizes or size distributions, phase processing circuitry uses the known particle size distributions and the measured phase distributions to determine certain coefficients which are stored in the phase processing circuitry. These coefficients are later used to generate size distribution functions, based on phase distribution functions obtained by measuring multiple phase values generated by stochastic particles of unknown size. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a model in a process of Drennen, III et al in view of Hammann et al to determine certain coefficients for storing in the phase processing circuitry with the expectation of

providing the desired correlations between particle size and coating process parameters, since Naqwi teaches that process can be investigated first on model to control a real process.

Drennen, III et al in view of Hammann et al in view of Naqwi fails to teach that a model of fluidized bed coating process for determining certain coefficients for storing in the phase processing circuitry, can be made by investigating a fluidized bed coating of a single particle or plurality of particles suspended on an upwardly directed gas flow.

Applicants' admitted art of Link et al teach that a coating process can be investigated first on process of coating a single particle in a fluidized bed by suspending the single particle on an upwardly directed gas flow, to determine influence of different process parameters on the thickness and morphology of resulting coating, and then using the obtained data for controlling a coating process in industrial fluidized bed (See page 3, lines 3-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out coating process of Drennen, III et al in view of Hammann et al in view of Naqwi by first investigating a coating process of a single particle in a fluidized bed model, i.e. suspending the single particle or plurality of particles on an upwardly directed gas flow and spraying (a succession of) liquid droplets of a coating material on the single particle or plurality of particles, with the expectation of providing the desired data relating to influence of different process parameters on the thickness and morphology of resulting coating, since Applicants' admitted art of Link et al teach that a coating process can be investigated first on process of coating a single particle in a fluidized bed by suspending the single particle on an upwardly directed gas flow, to determine influence of different process parameters on the

thickness and morphology of resulting coating, and then using the obtained data for controlling a coating process in industrial fluidized bed.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30, Mo-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for all communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

ETsoy

Elena Tsoy
Examiner
Art Unit 1762

January 12, 2004